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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,549	10/18/2004	Takahide Ohishi	08959.0010	9316

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EXAMINER	
PETERSEN, CLARK D	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,549	OHISHI ET AL.	
	Examiner	Art Unit	
	Clark D. Petersen	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) *8-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of claim 7 now including claims 12-13 in the reply filed on 9 March 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9 March 2007.

Claim Rejections - 35 USC § 112

Claim 7 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide reasonable written description for polypeptides of SEQ ID NO: 2 or 4 in which 1 to 15 amino acids are deleted, substituted, or inserted, and additionally does not provide support for a method wherein the polypeptide has 80% or greater homology. For the same reason, the specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, no characteristics are provided to support the invention of claims 7 and 12-13.

Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus of any polypeptide with 80% homology to, or 1 to 15 amino acid substitutions in, SEQ ID NO: 2 or NO:4.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed sequence or substitutions of the encompassed genus, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of

isolation or identification. Adequate written description requires more than a mere statement that a claim is part of the invention and reference to a potential method of practicing it.

There is no mention in the instant specification of which amino acids one of ordinary skill in the art would substitute and maintain a functional polypeptide that would provide a useful tool in an assay for insulin content enhancement. For example Guo et al (PNAS, 22 June 2004) teach that single random amino acid changes can abrogate enzyme function, and that the probability of a random change compromising function is about 34% for each change (see Results and Discussion, pp. 9205, col. 2, to 9206, col. 2, for example). It is well known in the art that once the functional domains of proteins are mapped, site directed mutagenesis can be performed, such that certain amino acids can be substituted that completely change the functional character of the enzyme, whereas substitutions in other locations can have no effect. Applicants have offered no specificity in their instant specification that supports a "blanket" claim that any protein within 80% homology, or containing 1 to 15 substitutions of SEQ ID NO:2 or :4 is suitable in the instant invention. There is no indication as to which amino acid substitutions, insertions, or deletions are possible which maintain an ability to "exhibit activity of promoting insulin production by activation". The Applicants do not provide even a single example of a polypeptide in which the amino acid sequence deviates from either SEQ ID NO:2 or NO:4.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Applicants do not define "activation" as recited in claim 7, steps (C) and (D) for example. There is no step elucidating how one of ordinary skill in the art would determine whether a polypeptide of the instant invention is activated or not. For that reason, there is no guidance to provide for one to select a compound, as recited in instant claim 12, or confirming that the selected substance activates the polypeptide, as recited in claim 13.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fehmann et al (Endocrinology, 1992). The teachings of Fehmann et al recite all the limitations in the claims, as guided by the instant specification. Fehmann et al teach that it has been previously demonstrated the GLP-1 is an insulin secretagogue when

administered to pancreatic β-cells. Additionally, it is known that intracellularly the GLP-1 signal is mediated by an increase in cyclic AMP (see Introduction, for example). They demonstrate additionally that GLP-1 administration to βTC-1 cells results in an increase in insulin promoter activity. They also test the ability of several cAMP analogues to cause the same increase in insulin promoter activity (see Results, pp. 161-2, and Fig. 1, as examples). The instant specification recites that β-cells express the polypeptide of SEQ ID NO:2 or 4 (depending on the species) (see p.14 last paragraph to p. 15 line 1; additionally, see Example 5, p. 32). Therefore the compound administration, measurement of cAMP, and measurement of insulin promoter activity taught by Fehmann et al inherently anticipate the instant claims.

Therefore the teachings of Fehmann et al are deemed to anticipate the instant claims 7, 12, and 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonini et al (US 6,221,660 B1, issued 24 Apr 2001).

Bonini et al disclose the sequences for rat and human G protein coupled receptor SNORF25, and these sequences match exactly the sequences of instant SEQ ID NO:2

and 4 (see Figs 1A-B; see Figs 3A-B, as examples). They teach that it is well known in the art that retinoids are well known to modulate pancreatic function; for example retinoic acid is required for insulin secretion from isolated islets and from insulinoma cells (see col. 2, lines 16-20, for example). They disclose that SNORF25 is responsive to retinoic acid, and causes an accumulation of cyclic AMP in response to retinoic acid (see Fig. 6; see col. 34, lines 37-58; see col. 10, lines 7-14, as examples). They also teach that SNORF25 is most highly expressed in pancreatic tissues (see col. 45, lines 45-55; see Table 1, col. 46, as examples).

A person of ordinary skill in the art at the time the invention was made would have been motivated to screen for compounds that increase cAMP and insulin promoter activity in cells that express SEQ ID NO:2 or 4 because Bonini et al teach that these sequences are expressed in insulin-producing tissues and they produce cAMP, which is a known activator of insulin promoter activity, in response to retinoic acid, a compound which is known to stimulate insulin production.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to screen for compounds that activate SEQ ID NO:2 or 4 as means of increasing insulin production.

Conclusion

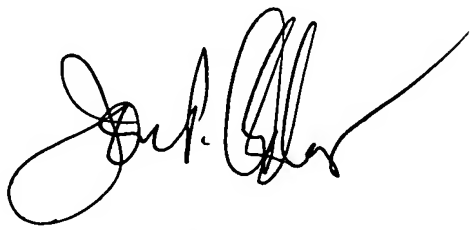
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
5/10/2007



Jon Weber
Supervisory Patent Examiner